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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/332,063	06/14/1999	LARS HOLMGREN	3362-0101P	2465

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/26/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/332,063

Applicant(s)

HOLMGREN ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,26-33 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) 26-29, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 30-33, 35 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Claims 1, 3-7, 9-33 and 35-38 are pending.

Claim 8 has been cancelled.

Claims 30 and 35 have been amended.

Claims 26-29, 36 and 37, drawn to non-elected inventions are withdrawn from examination.

Claims 1, 3-7, 30-33, 35 and 38 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objection

Claim Objections

3. The objection of claim 8 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of claim 7 is withdrawn in light of the cancellation of claim 8.

Claim Rejections - 35 USC § 112

4. The rejection of claims 1, 3-6, 30-33, 35 and 38 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Big-3 (SEQ ID NO: 4), a recombinant fragment of ABP-1 (SEQ ID NO: 2), an isolated human protein having anti-

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angiogenic activity and a receptor for a N-terminal fragment of plasminogen comprising human angiostatin (kringle domains 1-4) and plasminogen (kringles 1-5), does not reasonably provide enablement for any isolated human protein or fragment of ABP-1 which is capable of functioning as an anti-angiogenic molecule and a receptor for a N-terminal fragment of plasminogen comprising kringle 5 is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants assert that they have described an assay that would allow one of skill in the art to screen for the broadly claimed protein and "...submit that one could make and use the invention commensurate in scope with the claimed invention without undue experimentation". Applicants also aver that the Examiner has failed to meet the burden of presenting a *prima facie* case. These arguments and points of view have been carefully considered but found unpersuasive.

As of record in Paper number 24, mailed December 13, 2003 Applicants' specification supports the fragment of ABP-1 human receptor identified as SEQ ID NO: 4 (also regarded as Big-3), which is capable of binding kringles 1-4 and kringles 1-5. As currently written the claims broadly encompass a number of proteins and the exclusive binding of kringle 5. There are insufficient teachings in the specification that suggest that proteins or fragments other than Big-3 are able to exhibit anti-angiogenic activity and capable of serving as a receptor for N-terminal fragments of plasminogen, and while the claims present the function of the unidentified proteins the broad claims do not embrace proteins identified by structure. The proteins are not structurally characterized,

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thus the specification does not provide sufficient guidance enabling for the breadth of the claims. It is clear from the specification that certain residues are shown to be particularly important to the biological and structural properties of the claimed protein and such residues may not be generally exchanged. Notwithstanding, the nature (i.e. structure, function, avidity, etc.) of these broad class of proteins would be unpredictable. The broadly claimed protein read on variants, fragments and homologs and the specification has not presented sufficient teachings that fragments from ABP-1 other than Big-3 are capable of presuming function and corresponding structure to enable the breadth of the claim. Accordingly, for the reasons of record and set forth above the rejection is maintained.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alana M. Harris, Ph.D.
July 16, 2003



ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600